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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/423,035	01/13/2000	GERALD F. JOYCE	TSRI463.4	6257

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EXAMINER

LACOURCIERE, KAREN A

ART UNIT	PAPER NUMBER
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1635

27

DATE MAILED: 03/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/423,035

Applicant(s)

JOYCE ET AL.

Examiner

Karen A. Lacourciere

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 23 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-22 and 25-46 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

In response to applicant's telephone call on 03-04-2004 regarding the last Office action, the following corrective action is taken. Applicant called to request a new Office action summary for the Office action mailed 02-10-04, as the time to reply was inadvertently left blank. This supplemental Office action is identical to the Office action mailed 02-10-2004, but the time to respond has been provided on the Office action summary sheet.

The period for reply of 1 MONTHS set in said Office Action is restarted to begin with the mailing date of this letter.

Election/Restrictions

Applicant's election with traverse of SEQ ID NO: 121 and Formula II, SEQ ID NO: 122 in Paper No. 24 is acknowledged. The traversal is on the ground(s) that the Examiner should have only required an election of one catalytic DNA sequence 120, 121 and 122, and not between SEQ ID NO: 102-119, which are target sequences and further that the restricted inventions are linked by the common technical feature, that is first and second substrate binding sequences that flank a common core region, Formula I and Formula II. Applicant further argues that a lack of unity was not imposed in the International Search or Preliminary Examination and, therefore, should not be imposed herein.

Applicant's traversal has clarified the nature of the multiple sequences claimed in this national stage filing. The lack of unity is maintained, however, it is acknowledged

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that the Examiner did mischaracterize the catalytic DNA molecules, as claimed, and therefore, the requirement to elect a single catalytic DNA molecule is clarified, as follows.

Although this lack of unity was not imposed in the International Search or Preliminary Examination, the Lack of Unity is proper. The search burden imposed on the Office for sequence searching has become increasingly more burdensome since the time of the International Search and Preliminary Examination and, therefore, it is necessary to impose the Lack of Unity at the National Stage filing, particularly since it is necessary to identify prior art that qualifies in a rejection in the National Stage filing, that may not have qualified as prior art in the International Search or Preliminary Examination.

Claims 23 and 24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 15.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

The claims are specifically directed to catalytic DNA molecules with two different stem structural motifs, Formula I and Formula II (SEQ ID NO: 122), and different sequence

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structures within those formulas, SEQ ID NO:120 or 121 and are further drawn to distinct specific catalytic DNA molecules which target different substrate RNAs (EG HIV-1, FIV, IGF-R, E100 ligase) and different regions within an RNA (eg. regions encoding different HIV proteins) and different regions within the same RNA, and inhibit the expression of different proteins or cleave a target protein to a different degree. These distinct and specific substrate RNAs are specified within SEQ ID NO: 102-119. Catalytic DNA molecules targeting each of these different substrate sequences, 102-109, each target a different substrate mRNA, different regions within target these mRNA and inhibit the expression of different proteins or cleave a target protein to a different degree.

This international searching authority considers that the international application does not comply with the requirements of unity of invention (Rules 13.1, 13.2, and 13.3) for the reasons indicated below:

According to the guidelines in Section (f)(i)(a) of Annex B of the PCT Administrative Instructions, the special technical feature as defined by PCT Rule 13.2 shall be considered to be met when all the alternatives of a Markush-group are of similar nature. For chemical alternatives, such as the claimed antisense sequences, the Markush group shall be regarded as being of similar nature when

(A) all alternatives have a common property or activity and

(B)(1) a common structure is present, i.e, a significant structure is shared by all of the alternatives or

(B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to an art recognized class of compounds in the art to which the invention pertains.

The instant catalytic DNA sequences, SEQ ID NO:102-121, and the formulas I and II (SEQ ID NO:122) are considered to be each separate inventions for the following reasons:

The sequences do not meet the criteria of (A), common property or activity and (B)(1) common structure, ie. significant structure shared by all the alternatives or (B)(2), art recognized class of compounds. Each sequence targets a different RNAs (EG HIV-1, FIV, IGF-R, E100 ligase) different regions within an RNA (eg. regions encoding different HIV proteins) and different regions within the same RNA. Each of the claimed catalytic DNAs have a different activity in that they cleave a different RNA and regulate the expression of different proteins. Even catalytic DNAs targeting the same gene have a different activity in that they cleave at a different location within the RNA and have different levels of cleavage activity, and regulate expression of a protein to a different extent. Each member of the class cannot be substituted, one for the other, with the expectation that the same intended result would be achieved.

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Further, although the catalytic DNAs have small regions in common (ie. stem region) the sequences do not meet the criteria of (B)(1), as they do not share, one with another, a significant common core structure, for example, the major portion of sequences with the catalytic DNA are not common between the claimed molecules and the region which determines the activity of the catalytic DNA, ie. the substrate binding region, is not common between the claimed DNA molecules. Accordingly, unity of invention between the catalytic DNA sequences is lacking and each sequence claimed is considered to constitute a special technical feature.

Further, a preliminary search of the sequence elected in Paper No. 24, demonstrates that there is a significant amount of prior art that discloses catalytic DNA molecules comprising the elected stem formulas, SEQ ID NO:121 and 122 and, therefore, this formula, set forth by the Inventor as the special technical feature, is not a novel contribution to the art and, therefore, does not constitute a special technical feature. For example, US Paten No. 6,361,941.

Therefore, Applicant must elect a single catalytic DNA molecule, SEQ ID NO:120 or 121, and one corresponding stem formula, I or II (SEQ ID NO:122) and one corresponding substrate sequences (one of SEQ ID NO:102-119), targeted by the elected catalytic DNA molecule in response to this Official action.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

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or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Lacourciere whose telephone number is (571) 272-0759. The examiner can normally be reached on Monday-Thursday 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (571) 272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Lacourciere
February 9, 2004


KAREN A. LACOURCIERE, PH.D
PRIMARY EXAMINER